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No. 92-173

In The
Supreme Court of the United States

OCTOBER TERM, 1992

EFAMOL, LTD.,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

REPLY BRIEF TO OPPOSITION

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TABLE OF CONTENTS

Page

A. The Ninth Circuit's Decision Heightens The Conflict In The Circuits Over Fed. R. Evid. 703 And *Frye* 2

B. The Supreme Court Should Resolve The Conflict As To Which Party Bears The Burden Of Proof On The GRAS Issue 6

C. The Misbranding Issue Has No Impact On The Reviewability Of The Other Issues In This Case . . . 8

Conclusion 10

TABLE OF AUTHORITIES

Page

Cases

Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986) 6, 7

Celotex Corp. v. Catrett, 477 U.S. 317 (1986) 6, 7

Clark v. J.M. Benson Co., Inc., 789 F.2d 282 (4th Cir. 1986) 7

Folks v. Secretary of Dep't of Health and Human Services, 825 F.2d 1259 (8th Cir. 1987) 7

Roe v. Wade, 410 U.S. 113 (1973) 9

United States v. 217 Cases . . . Efamol Evening Primrose Oil, No. 92-C-0584B (D. Utah filed June 1, 1992) 9

United States v. An Article Of Food, 752 F.2d 11 (1st Cir. 1985) 6

United States v. Article of Drug . . . 203 Paper Bags, 818 F.2d 569 (7th Cir. 1987) 9

Weinstein v. Bradford, 423 U.S. 147 (1975) 9

Statutes, regulations and rules

21 C.F.R. § 170.30(b) (1992) 5

21 U.S.C. § 321(s) (1992) 1, 3

Federal Rule of Evidence 703 . . . . . *passim*

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This case provides the necessary vehicle for this Court to resolve three critical legal issues upon which there exists a clear split in the courts of appeals: (1) whether it is improper for courts to use Rule 703 of the Federal Rules of Evidence to weigh conflicting expert testimony; (2) whether the enactment of Rule 703 eliminated the common-law *Frye* test; and (3) whether the Food and Drug Administration ("FDA") or manufacturers of food products bear the burden of proving in a seizure action that the food in question is "generally recognized as safe" ("GRAS") for its intended use within the meaning of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), 21 U.S.C. § 321(s) (1992).

The government in its Brief For The United States In Opposition ("Opp. Br.") does not deny the existence or importance of these conflicts. Instead, the government ignores the express reasoning of the Ninth Circuit's summary judgment decision, and argues that the decision did not turn on the court's interpretation of Rule 703 and the *Frye* test, or on who bears the burden of proof on whether a seized food product is GRAS. To support this interpretation, the government concocts various justifications for the Ninth Circuit's decision, none of which is found in the text of that decision.

The government's recasting of the Ninth Circuit's opinion cannot hide what the court actually did. The court unequivocally invoked the outdated *Frye* test and Rule 703 in its wholesale rejection of the petitioner Efamol, Ltd.'s ("Efamol's") expert testimony, and held that summary judgment against Efamol was appropriate because Efamol could not carry *its burden of proof* at trial. This case is thus particularly appropriate for this Court to resolve the conflict and confusion over Rule 703, the *Frye* test, and the burden of proof issue.

A. The Ninth Circuit's Decision Heightens The Conflict In The Circuits Over Fed. R. Evid. 703 And *Frye*

The government admits that the courts of appeals are divided on whether the enactment of Rule 703 of the Federal Rules of Evidence abolished the common-law *Frye* test. Opp. Br. at 5. The government argues, however, that the *Frye* issue and Rule 703 are not relevant to this case because "[t]he [FDC] Act . . . settles the dispute over whether a novel scientific theory or technique must have 'gained general acceptance' in the context of litigation over components of food by requiring that the safety of the substance must be 'generally

recognized' by experts." *Id.* at 5.[1] The government alleges further, without any textual support from the Ninth Circuit's decision or citation to any standards normally used in GRAS evaluations, that "[t]he court of appeals reasonably concluded that petitioner's evidence did not meet the rigorous scientific standard established by the [FDC] Act and its regulations." *Id.* at 5-6. This attempt to paper over the Ninth Circuit's opinion does not work.

The Ninth Circuit summarily rejected the extensively articulated expert testimony supporting the GRAS status of evening primrose oil ("EPO"), which evidence is unequivocally of the kind FDA itself uses to consider GRAS status. Efamol has been unable to locate any other case in which so much expert testimony from such eminently qualified experts has been rejected in such a cavalier manner, with no consideration given to the criteria that normally apply to the scientific issue at hand.

How the Ninth Circuit rejected this expert testimony is a matter of record — the court invoked both the *Frye* test and Rule 703. Opinion at A-8-9. The Ninth Circuit began its discussion of Efamol's expert testimony by paraphrasing statutory and regulatory provisions pertaining to GRAS evaluations, and then cited two types of evidence that Efamol's experts considered to reach the conclusion that EPO is GRAS.

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[1] The government attempts to muddy an already standardless opinion. The Ninth Circuit's thoughtless citation to the FDC Act does not excuse its improper reliance on *Frye* and incorrect application of Rule 703. Further, the test in *Frye* — whether a "novel scientific technique" has gained "general acceptance" — and the test for GRAS status are not the same. The *Frye* test is a *judicially derived* rule of evidence that places the *court* in the position of determining "general acceptance" of "novel scientific techniques," presumably to protect the court from reliance on views that the majority of scientists would regard as unacceptable. In GRAS evaluations, on the other hand, *Congress* has appointed *qualified experts*, not the court, as the proper body for determining GRAS status. 21 U.S.C. § 321(s).

Id. at A-8. The court held that "[t]hus, the opinions of Efamol's experts were contaminated by their consideration of unsuitable evidence." *Id.* at A-8-9. The court next held that "additional data relied on by Efamol is insufficient under Rule 703 of the Federal Rules of Evidence." *Id.* at A-9 n.4.[2] The court then invoked the *Frye* test to support its rejection of all Efamol's expert testimony. *Id.* at A-9. The government now argues that, in addition to *Frye* and Rule 703, the court also invoked the FDC Act and FDA regulations.[3]

Efamol agrees that the FDC Act, FDA's regulations, and the FDA's own published record of GRAS evaluations define the standard for determining whether a food substance such as EPO is GRAS. The Ninth Circuit nonetheless ignored that standard. Petition For Writ Of Certiorari ("Pet.") at 4-7. Instead, the court improperly superimposed the outdated *Frye* test on the FDA's established GRAS standards, and effectively repealed FDA's regulatory criteria for determining whether a substance is GRAS. Opinion at A-8-9. In addition, the court misused Rule 703 of the Federal Rules of Evidence to weigh and reject Efamol's expert testimony. Rule 703 is satisfied if the expert's testimony is based on the type of data experts in the field customarily use in rendering an opinion on the subject at issue. Rule 703 does not address the reliability or general acceptance of an expert's methodology. Pet. at 14-23.

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[2] The Ninth Circuit indirectly criticized Efamol for not providing to the government certain publicly available data that Efamol's experts found through their research, data that the government could have challenged through depositions but did not. Opinion at A-9 n.4. The court did not make clear its rationale for rejecting these data under Rule 703. However, the court deemed the data "insufficient" rather than "inadmissible" under Rule 703, showing that the court improperly usurped the jury function and *weighed* the expert testimony.

[3] Notably, the government does not make any attempt to show that the provisions in question were properly applied.

If the Ninth Circuit had, as the government alleges, properly focused on the FDC Act and FDA's own publicly acknowledged criteria for determining whether a substance is GRAS, it would have recognized that FDA regulations specifically permit experts to consider unpublished data as corroborating a substance's safety in GRAS evaluations. 21 C.F.R. § 170.30(b) (1992) (GRAS status "may be corroborated by unpublished studies and other data and information"), A-23.[4] The court would also have recognized that FDA's published record of GRAS evaluations establishes that FDA and competent food safety experts routinely depend on unpublished data and data from drug studies to perform GRAS evaluations. Pet. at 5-7 and A-24-138.

Furthermore, Efamol's experts testified that the data on which the experts relied to make their determination that EPO is GRAS are of the type reasonably relied upon by experts in the field. Pet. at 9 & n.10. In applying *Frye* and Rule 703, the Ninth Circuit never bothered to determine how trained experts perform GRAS evaluations.

In the face of clear guidance from the FDC Act, FDA regulations, FDA practice, and the testimony of Efamol's experts, the Ninth Circuit misused both the *Frye* test and Rule 703 to evaluate and to reject Efamol's expert testimony. The court's offhanded application of these rules underscores the need for the Supreme Court's guidance on the proper application of *Frye* and Rule 703.

This Court needs to clarify that Rule 703 is not a tool for judges to weigh conflicting expert testimony, and that the *Frye* test has been superseded by the Federal Rules of Evidence. *See* Pet. at 14-25.

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[4] The Ninth Circuit's Opinion, if allowed to stand, revokes this regulation. Opinion at A-8-9 (holding unpublished data to be "unsuitable evidence").

B. The Supreme Court Should Resolve The Conflict As To Which Party Bears The Burden Of Proof On The GRAS Issue

The government also contends that the conflict in the circuits over which party bears the burden of proof on the issue of GRAS status "is not properly presented in this case" because "[t]he court's passing references to the burden of proof in GRAS cases, like its reference to Rule 703, did not affect its decision." Opp. Br. at 6, 8. The government maintains, without any support in the record or logic, that the decision would have been the same however the burden of proof was allocated. *Id.*

The Ninth Circuit's opinion establishes that allocation of the burden of proof was critical to the ultimate decision of the court to uphold the district court's summary judgment decision. The Ninth Circuit held specifically that "'[t]he burden of proving general recognition of safe use is placed on the proponent of the food substance in question.'" Opinion at A-7 (*quoting United States v. An Article Of Food*, 752 F.2d 11, 15 (1st Cir. 1985)).

The court then proceeded with its consideration of the evidence offered by both parties. After rejecting Efamol's expert testimony, the court stated that "the government's witnesses testified that there is insufficient published scientific literature showing that EPO is safe and there is insufficient animal or human testing of EPO's use as a dietary supplement." Opinion at A-9. Finally, citing this Court's decision in *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986), the court held that "summary judgment was appropriate because Efamol failed to make a showing sufficient to establish the existence of an essential element to its case, *and on which it bears the burden of proof at trial.*" Opinion at A-9 (emphasis added).

The government alleges that the Ninth Circuit actually *meant* to apply the principles in *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986), even though the Ninth Circuit

specifically cited *Celotex*. Opp. Br. at 7-8.[5] The government's argument concerning *Anderson* confuses the burdens associated with a motion for summary judgment with the burden of proof specified in the underlying substantive law. Contrary to the government's contention, the Ninth Circuit clearly did apply *Celotex* and then incorrectly upheld the district court's grant of summary judgment based on a misallocation of the burden of proof under the substantive law of the FDC Act.

Celotex holds that a nonmoving party must sufficiently demonstrate the existence of an element essential to its case on which it will bear the burden of proof at trial. 477 U.S. at 322. Because the FDC Act and its legislative history establish that FDA has the burden of proving that EPO is not GRAS, Pet. at 25-29, the court clearly erred in stating that Efamol had the burden of proof on this issue, and in concluding that summary judgment was justified because of Efamol's failure to meet its burden.[6]

The Ninth Circuit's mistake in allocating the burden on the GRAS issue alone warrants reversal. *See, e.g., Folks v. Secretary of Dep't of Health and Human Services*, 825 F.2d 1259, 1261 (8th Cir. 1987) (failure to acknowledge shift in burden of proof in disability benefits case was error resulting in reversal of district court summary judgment); *Clark v. J.M. Benson Co., Inc.*, 789 F.2d 282, 285 (4th Cir. 1986) (directed verdict in employee compensation case was reversible error when

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[5] The government maintains specifically that "[a]lthough the court of appeals twice referred to *Celotex* . . . the *Celotex* principle does not apply in this case." Opp. Br. at 8.

[6] The Ninth Circuit gave no indication that it considered FDA's evidence sufficient to warrant summary judgment if the *government* bore the burden of proof under the substantive law. Therefore, the allocation of the burden was critical to the court's decision.

district court improperly assigned to plaintiff burden of proving non-administrative status).[7]

C. The Misbranding Issue Has No Impact On The Reviewability Of The Other Issues In This Case

Efamol has maintained throughout this litigation that the seized product was properly labeled, but that the product's labeling is not the real issue: the labeling can easily be changed, either on the seized product or on the next shipment of EPO, *if* the real issue in this case — whether EPO can be legally marketed as a GRAS substance — is ultimately decided in Efamol's favor. Pet. at 29-30. The government does not attempt to refute Efamol's argument that the Ninth Circuit's decision on the misbranding issue is incorrect, but merely quotes what the court already said. Opp. Br. at 9. Furthermore, the government's arguments on the impact of the court's misbranding ruling support Efamol's argument that this issue need not be addressed by this Court.

The government argues that, even if the GRAS issue were decided in Efamol's favor, this *might* be of no use, because, the government speculates, the seized product may have spoiled in the interim. Opp. Br. at 9 n.4. This argument supports Efamol's point. The physical condition of the seized product, whether it be the labeling, the product's expiration, or

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[7] The government quibbles over whether a "sufficient" conflict of opinion actually exists on the issue of who bears burden of proof because no court has yet fully analyzed the issue. Opp. Br. at 9 n.4. This is beside the point. There is no question that the Ninth Circuit's allocation is in conflict with other circuits' allocation of the burden on FDA. Pet. at 28-9. The statutory provisions in question and the legislative history leave no room for doubt: FDA bears the burden of proof. *Id.* at 27-8. The conflict undermines the Ninth Circuit's decision. Further, this issue is ripe for Supreme Court review not only as a result of a conflict in the circuits, but because of the importance of this issue to this case and the food industry in general.

even the product's destruction, has no bearing on the GRAS issue — the issue that will determine whether EPO can be marketed in the United States in the future.

It is settled law that technical problems such as mootness, or in this case a potential alternative basis for judgment that will never arise again, should not bar review where there is a "reasonable expectation that the same complaining party would be subjected to the same action again." *Weinstein v. Bradford*, 423 U.S. 147, 149 (1975) (per curiam); *see also Roe v. Wade*, 410 U.S. 113, 125 (1973); *United States v. Article of Drug . . . 203 Paper Bags*, 818 F.2d 569, 572-74 (7th Cir. 1987).

The government does not argue that the misbranding issue has any future application to the marketing of EPO in the United States, or that EPO can be legally marketed if properly labeled. In fact, the government has recently filed another seizure action to prevent the marketing of EPO made by a company that has distributed Efamol's products, alleging that the EPO product at issue, clearly labeled as EPO, is an unapproved food additive. The government does not allege that the EPO is misbranded. *United States v. 217 Cases . . . Efamol Evening Primrose Oil*, No. 92-C-0584B (D. Utah filed June 1, 1992). The government's action removes any argument that the labeling of the seized product has an impact on future marketing.

The Ninth Circuit's determination of the misbranding issue was incorrect. Nonetheless, misbranding has no bearing on the real issue in this case, and the misbranding issue need not be addressed by this Court.

Conclusion

For the foregoing reasons, certiorari should be granted.

Respectfully submitted,

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